REMARKS

Claim 1-38 were pending in the subject application. Claims 5, 7-8, 22-23, 26, 32-34 and 37 are withdrawn from consideration by the Examiner as directed to non-elected species. By this amendment, Claims 17 and 32-34 have been cancelled without prejudice or disclaimer, and Claims 1, 7, 9, 18, 22, 24, 31 and 37-38 have been amended. Applicants maintain that the amendments to the claims do not raise an issue of new matter. Support for the amendments to Claim 1 can be found at least in Claims 7, 9 and 17. Support for the amendment so Claim 31 can be found at least in Claims 32-34. Support for the other claim amendments can be found at least in the previous version of the claims.

The specification has been amended to indicate registered trademarks. Applicants maintain that the amendments to the specification do not raise an issue of new matter.

Entry of the amendments is respectfully requested.

Objections to the Specification

The specification was objected to for not indicating trademarks. Reconsideration and withdrawal of this objection are respectfully requested in view of the amendments to the specification made herein above.

Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner indicated that Claim 31, line 5, recited "the gene" without providing sufficient antecedent basis for this limitation. Reconsideration and withdrawal of this rejection are respectfully requested in view of the amendments to Claim 31 made herein above.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-4, 6, 10-21, 25, 27-31, 35, 36 and 38 are rejected under the enablement and written description requirements for the full breadth of the claims.

Reconsideration and withdrawal of these rejections are respectfully requested in view of the amendments and remarks presented herein.

Independent Claims 1 and 31 have been amended to require that the agent that is effective to increase transcription of the gene is a fluorinated quinolone or thioguanine.

Claim 1 also requires the administration of an agent that is effective to suppress a premature stop codon. The use of aminoglycoside antibiotics to suppress premature stop codons associated with a variety of disorders is described in the present application in paragraphs [0006] and [0012]-[0013], as well as for example in paragraphs [0010]-[0011] in Wilde et al., US 2004/0067900, of record. The use of the agent PTC124 to suppress premature stop codons in different disorders is described in the present application in paragraph [0012]. The use of PTC124 is further described in references submitted in the accompanying Supplemental Information Disclosure Statement (SIDS) (Du et al. 2008, Hirawat et al. 2007, Kerem et al. 2008, Selleck Chemicals catalog, Welch et al. 2007). Furthermore, Wilde et al., US 2004/0067900 disclose the use of a variety of small molecules for suppressing premature stop codons (see, e.g., Summary of the Invention and 4.1 Compounds of the Invention).

Genetic diseases associated with nonsense mutations are described, for example, in the present application in paragraphs [0005]-[0006], [0020], [0021], [0023] and [0029], as well as in paragraphs [0202-[0214] in Wilde et al., US 2004/0067900, and in Guilford et al. 1996, Laumonnier et al. 2004, and Yeowell and Walker 1997 submitted in the accompanying SIDS.

Claim 31 has been amended to require administration of specific agents effective to suppress an exon skipping mutation and/or correct a defect caused by the exon skipping

mutation. These agents are described in paragraph [0026] in the present application. Exon skipping mutations are associated with a variety of genetic disorders (see, e.g., paragraph [0026] in the present application, and the following references in the SIDS: Booms et al. 1999, Durlez et al. 1994, Fernandes et al. 1998, Folgi et al. 1999, Hirano et al. 1998, Macoska et al. 2001, Mercuri et al. 2002, Nicholls et al. 1996, Tiller et al. 2001, Spayde et al. 2000, Vally et al. 1995, and Yeowell and Walker 1997).

Rejections under 35 U.S.C. §102/103

Claims 1, 6, 10-16, 19-21, 27-31, 35-36 and 38 are rejected under 35 U.S.C. §102(e) as being anticipated by Wilde et al., US 2004/0067900.

Claims 2-4 and 25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wilde et al., US 2004/0067900.

Reconsideration and withdrawal of these rejections are respectfully requested in view of the amendments and remarks presented herein.

Claim 1 has been amended to incorporate the features of Claim 17, which is not included in the rejections.

It is also noted that Wilde teaches the use of specified compounds to treat or prevent diseases associated with nonsense mutations. Wilde teaches that the compounds of their invention can be administered in combination with a laundry list of other agents, including other therapeutic agents such as non-opioid analgesics, non-steroid anti-inflammatory agents, antiemetics, beta-adrenergic blockers, anticonvulsants, antidepressants, Ca^{2+}-channel blockers, anticancer agent and mixtures thereof [paragraph 0220]; anticancer agents such as alkylating agents, nitrogen mustards, folate antagonists, purine antagonists, pyrimidine antagoinists, spindle poisons, topoisomerase inhibitors, apoptosis inducing agents, angiogenesis inhibitors, podophyllotoxins, nitrosoureas, cisplatin, carboplatin, interferon, asparginase, tamoxifen, leuprolide,

flutamide, megestrol, mitomycin, bleomycin, doxorubicin, irinotecan and taxol [paragraph 0221]; and antibiotics such a macrolide (e.g., tobramycin), a cephalosporin (e.g., cephalexin, cephradine, cefuroxime, cefprozil, cefaclor, cefixime or cefadroxil), a clarithromycin (e.g., clarithromycin), an erythromycin (e.g., erythromycin), a penicillin (e.g., penicillin V) or a quinolone (e.g., ofloxacin, ciprofloxacin or norfloxacin), where in a preferred embodiment, the antibiotic is active against *Pseudomonas aeruginosa* [paragraph 0222].

It is noted that Wilde teaches the use of ofloxacin as an *antibiotic*. Wilde does not enable the use of ofloxacin as an agent that is effective to increase transcription of a gene. Nor is it necessarily present from Wilde that the use of ofloxacin as an antibiotic would be effective to increase transcription of a gene. In particular, it is noted that it is known that quinolone drugs can cause damage to DNA (see, e.g., Enzmann et al. 1999 and Thomas et al. 1990 in accompanying SIDS).

Independent Claim 31 has been amended to be directed to a specified method for enhancing production in a subject of a functional protein from a gene, where production of the protein is disrupted by an exon skipping mutation, which is not taught or suggested by Wilde.

Supplemental Information Disclosure Statement

This Supplemental Information Disclosure Statement is being filed to supplement the Information Disclosure Statements filed on July 20, 2006 and April 13, 2009 in connection with the subject application. In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the references that are listed on the attached Forms PTO/SB/08B and attached hereto.

CONCLUSIONS

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the objections and rejections in the December 28, 2009 Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

A check for $180.00 is enclosed for the fee for filing an Information Disclosure Statement. No additional fee is deemed necessary in connection with the submission of this reply. However, if any fee is required to maintain the pendency of the subject application, authorization is hereby given to withdraw the amount of any such fee from Deposit Account No. 01-1785.

Respectfully submitted,

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By _____
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